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人血浆中多潘立酮的含量测定及药物动力学考察

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摘要
目的 建立测定人血浆中多潘立酮的高效液相－串联质谱法，并将其应用于健康人体的药动学研究。方法 20名健康男性受试者单剂量口服多潘立酮10 mg后，以氨溴索为内标，进行LC－MS/MS测定。色谱柱为 XTerra?MS C18，流动相为甲醇-水-甲酸（95:5: 0.05，v/v/v），流速为100 mL·min-1；质谱条件为电喷雾离子源，正离子方式多反应扫描，离子选择通道分别为m/z 426.4 → m/z 175.0（多潘立酮）和m/z 379.0→ m/z 264.0（氨溴索）。结果 多潘立酮测定方法的线性范围为0.5～50 ng·mL-1，日内和日间精密度(RSD)均小于13.5 %。多潘立酮片在中国健康受试者体内呈二室模型特征，主要药代动力学参数t max为(0.75±0.24) h,ρmax为(17.0±4.83) ng·mL-1,t1/2为(9.78±4.66) h,AUC0-t为(105±28.6) ng·h·mL-1 ,AUC0-∞为(121±45.9) ng·h·mL-1。结论 本法简便、准确、灵敏，适用于多潘立酮的人体药动学研究。

关键词 药剂学 多潘立酮 液相－串联质谱 血药浓度 药动学

分类号 R94

Determination of domperidone concentration in human plasma by LC-MS-MS and its pharmacokinetics

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Abstract
Objective To establish a liquid chromatography-tandem mass spectrometry（LC-MS-MS） method for the determination of domperidone in human plasma and to study its pharmacokinetics in healthy volunteers. Methods After a single dose oral administration of domperidone 10 mg to 20 healthy Chinese male volunteers，the plasma concentrations of domperidone were determined by LC-MS-MS by taking ambroxol as internal standard. Chromatography was performed on a XTerra?MS C18 column with a mobile phase consisting of methanol-water-formic acid（V:V:V=95:5:0.05）,delivered at 100 mL·min-1. A triple quadrupole tandem mass spectrometer equipped with Turbo Ionspray Source was used as detector and was operated in the positive ion mode. Multiple reaction monitoring using the precursor to produce ion combinations of m/z 426.4→m/z 175.0 and m/z 379.0→m/z 264.0 was performed to quantify domperidone and the internal standard ambroxol, respectively. Results The calibration curve of domperidone was linear in the range of 0.5-50 μg·L-1. The intra-day and inter-day precision (RSD) were below 13.5 %. The pharmacokinetic characteristics of domperidone were fitted with a two-compartment model. The main pharmacokinetic parameters were as follows: tmax (0.75±0.24) h；ρmax(17.0±4.83) μg·L-1；t1/2 (9.78±4.66) h； AUC0-t(105±28.6) μg·h·L-1；AUC0-∞ (121±45.9) μg·h·L-1. Conclusion LC-MS-MS method established in this study is simple and sensitive with better accuracy, which is adapted to the study of pharmacokinetics of domperidone.
Key words pharmaceutics pharmacokinetics LC-MS-MS domperidone plasma concentration

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